

REMARKS

Status of Claims and Amendment

Upon entry of this amendment, which is respectfully requested, claims 1-4 and 7-20 will be amended. Claims 1-21 are all the claims pending in this application, and are rejected. Claims 10 and 12 are withdrawn from consideration as being directed to a non-elected invention.

Claims 1, 15, and 16-20 have all been amended in a similar manner to further clarify that the method of performing interactive clinical trials for testing a new drug for cancer related studies comprises “obtaining data” for the pharmacodynamics of a drug from *in vitro* studies of the effect of the drug in animal cells, and optionally *in vivo* studies in animals, and obtaining data for the pharmacokinetics of the drug from *in vivo* studies in animals so that eventually, simulated computer predictions are compared with actual clinical results and the comparison is used to adjust the computer model, an *in silico* patient. Support for the amendments to claims 1, 15, and 16-20 may be found throughout the specification, for instance, at page 12, paragraphs [22] and [23], page 17, paragraph [53] and [54], page 21, paragraphs [68] and [69], and original claim 14.

Claims 2-4 and 7-14 are amended to be consistent with the amendments to claim 1.

No new matter is added.

Summary of Personal Interview with Examiner Conducted on August 10, 2009

Applicants thank Examiner Clow for conducting a personal interview with Applicants’ representatives, Chid S. Iyer and Tu A. Phan-Kerr.

During the interview, the Examiner indicated that the claimed invention involves a “transformation” that satisfies the transformation prong of the “machine-or-transformation” test required in *Bilski*. The Examiner understood that the although the presently claimed method involves a mathematical algorithm, the algorithm is used to transform the data obtained *in vitro*

or *in vivo* from a pre-clinical or clinical phase to provide an optimal treatment protocol obtained by an interactive clinical design. Nevertheless, the Examiner suggested, for instance, amending claim 1 to further clarify that the claimed invention involves an active step of obtaining *in vitro* or *in vivo* data that so that the data that is obtained as part of the method is “transformed” to provide an optimal treatment protocol. In view of the above, the Examiner stated that she believes the claimed invention meets the test in *Bilski* to be allowable.

Response to Rejections Under 35 U.S.C. § 101

Claims 1-9, 11 and 13-21 are rejected under 35 U.S.C. § 101, because the claimed invention is allegedly directed to non-statutory subject matter for the same reasons set forth in the Office Action mailed December 31, 2008. For brevity, these reasons are not reiterated herein.

In addition, the Office Action asserts that Applicants’ arguments that the method steps do not merely “encompass *in silico* results with no specific output” is not persuasive because the steps of performing a clinical trial such that the data may be used for computer simulation, is a data gathering step. The computer model is asserted to not be limited to a specific model so that the fail the machine-or-transformation test.

In response, Applicants note that as discussed during the personal interview with on August 10, 2009, *In re Bilski* is not applicable to Applicants’ invention. The Opinion referred to by the Office Action involves a method of hedging risks in commodities trading, not a method of performing interactive clinical trials for testing a new drug for cancer related studies, resulting in clinical trial designs, as presently claimed. Judge Michel, the author of the Opinion, indicated, *Bilski* did not discuss those areas of art and the facts did not provide an opportunity to address those arts (referring specifically to business methods, software and bioinformatics, and thus,

biotechnology and chemistry). See BNA Journal, Number 139, July 23, 2009, ISSN 1522-4325, TODAY'S UPDATE, Conferences, "Chief Judge Michel Says Commentary Reading Too Much Into Bilski Opinion", submitted herewith¹. In the BNA article, Judge Michel commented that the Opinion was never intended to be applied rigidly or restrictively as to invalidate patents for whole areas of technology thereby significantly limiting the application of his Opinion and the holding in *Bilski*. Id. Further, with regard to processes that "transform a particular article into a different state or thing, [Judge Michel] noted that the concern of some that "article" implies something physical." That's not a reasonable construction of the word," he said." These comments by Judge Michel are consistent with the PTO's interpretation that the subject matter manipulated by a process does not have to be a physical object; it may be "intangible subject matter representative of or constituting physical activity or objects" so that there is a transformation or reduction of an article to a different state or thing. For example, an electrical signal representing data corresponding to a physical object or physical activity is appropriate subject matter for manipulation by a process. See PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" and "Legal Analysis to Support Proposed Examination Guidelines for Computer-Implemented Inventions".

In the present case, as previously argued, although the claimed method involves use of a mathematical algorithm, the claimed method involves a practical application of the raw data obtained either *in vitro*, *in vivo*, or from actual small clinical trials to provide an optimum treatment regimen or clinical trial design for cancer treatment that is representative of actual

¹ In accordance with M.P.E.P. § 609.05(c), the document cited herein in support of Applicants' remarks are being submitted as evidence directed to an issue raised in the Official Action, and no fee pursuant to 37 C.F.R. 1.97 or 1.98, or citation on a FORM PTO/SB/08A & B is believed to be necessary.

preclinical to Phase IV clinical trials without the expense and time loss usually associated with such full-scale studies. *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (“application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”).

Thus, Bilski did not discuss the art at issue and the facts did not provide an opportunity to address this art.

However, even if Bilski is applicable, the presently claimed method involves a mathematical algorithm that is used to transform the data obtained *in vitro* or *in vivo* from a pre-clinical or clinical phase to provide an optimal treatment protocol obtained by an interactive clinical design.

Furthermore, and solely to advance prosecution of the present application, the claims have been amended, as suggested by the Examiner during the personal interview, to further clarify that the claimed method includes an active step of obtaining *in vitro* or *in vivo* data. Applicants note that the data obtained is then “transformed” to provide an optimal treatment protocol.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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